



BTLock
NEXT GENERATION SYSTEM

MAR 27 2009

K083869

ABBREVIATED 510(K) SUMMARY

Submitter's name: BTLock S.r.l.
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Italy
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Date of this summary: December 9th, 2008
Name of the devices: BT-Tite CV3, Mini Implant, Mini Single, Slot Implant
Common or usual name: BT-Tite CV3, Mini Implant, Mini Single, Slot Implant
Classification name: Endosseous Implant (21 CFR 872.3640)

Opening remarks: BTLock is located in Alte Ceccato, a minor part of Montecchio Maggiore. In January 2007 Alte Ceccato was inglobated in the main town and since then the relative postal code (36041) is no longer in use. The new one is 36075. This is the reason why you will find some disagreement from this point of view in the documents we are submitting.

You will find different names of the company in the submission as well. You will see BTLock and Fidelm. It is the same company: Fidelm changed its name in BTLock in 2003 (see attachment n° 12).

Probably in the attachments and in the catalogues you will find different kind of surfaces (HA Coated, Acid-etched); we are not going to export them in the USA and therefore they are not part of this submission.

The major part of the products you see in the catalogue have already been approved by the FDA with the K073458. We registered recently at FURLS. This is our owner operator number: 10027925.

BTLock system is already registered as medical device in European union (CE, see attachment n° 41), Taiwan (DOH, see attachment n° 46), Brasil (ANVISA, see attachment n° 47, we are at pp.41), South Korea (KFDA, see attachment n° 48). BTLock quality system is certified by DNV (ISO 9001 and 13485, see attachments n° 43 and 44).

All products codes are included in BTLock Free Trade certificate (see attachment n° 45).

The legally marketed devices to which we are claiming substantial equivalence, according to 807.92, are the following: BT-Tite CV3, Mini Implant, Mini Single, Slot implant.

BT-Tite CV3

| BTLock device | Reference | Device name | Manufacturer |
|---------------|-----------|-------------|---------------|
| BT-Tite CV3 | K073458 | BT-Tite CV2 | BTLock S.r.l. |

Description of the device

BTLock implant are intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore chewing function to partially or fully edentulous patients. The main feature of BTLock implant system is an original and patented connection (US patent n° 6659700 B2 dated December 9th 2003, attachment n° 11). This connection has no compatibility with other systems. All prosthetic components and accessories are exclusive for BTLock implant system. It included BT-Tite One, BT-Tite CV2 and BT-Tite Standard lines which have been approved by the FDA with the 510(K) number 073458.

BT-Tite CV3 is an implant line which includes fixture and abutment joined together by a through screw. CV3 fixture is machined from titanium, with a deep thread, micro-grooves on the collar, 6 longitudinal long grooves along the body till the collar, DMA surface and a platform designed for the platform-switching. The surface treatment called DMA (which stands for *doppia mordenzatura acida*, that is double acid-etching) is obtained by the combination of sand-blasting and double acid-

etching. This treatment is absolutely equivalent to BT-Tite (no material is added, no changes in the material used for the treatment: just acid-etching is performed twice instead than once).

This line features a conical-cylindrical shape as the other fixtures of BTLock system. Therefore, because of this equivalence, I submitted the same tests carried for the other lines (BT-Tite One, BT-Tite CV2, BT-Tite Standard).

It is available in 3 diameters (3,75 – 4,5 – 5,5 mm) and 5 lengths (8 – 10 – 11,5 – 13 – 16 mm). The technical details of the product are included in its own drawing (see attachment n° 18).

See attachment n° 07 for the brochure of BT-Tite CV3 and the surgical handbook (attachment n° 10) for reference about the surgical protocol which is equivalent to that of the other fixtures of BTLock system.

Intended use

This fixture is intended to be used in maxilla or mandible, for single or multiple replacement, for post-extraction sites and where the implant would be immediately loaded. In case of post-extraction sites it has to be inserted some millimetres under the bone crest. It can be placed in the oral cavity in one or two stage surgical procedure. It is intended for single use only.

When selecting a candidate to implant treatment, some aspects should be carefully considered: patient's expectations and motivations, his/her general health conditions, and the oral hygiene.

Labeling

As the other BTLock lines, BT-Tite CV3 fixtures are packed together with a surgical screw, an assembling screw, and the implant carrier. Once these parts are assembled, they are put in a crystal vial, which is inserted in a blister pack. It is then sent to the gamma-ray sterilization. On the blister pack two little labels are stucked: one for the dentist's record and one for the patient's sheet. The blister pack is then put in a pasteboard package together with an information sheet (which is written in 4 languages: Italian, English, Spanish, Portuguese). On the pasteboard package another label is stucked, which contains the following information about: product description, product code, size (diameter, length), the colour-code (which refers to the diameter), expiry date, manufacturing date, batch number, CE mark, sterile mark, one-time use mark, the indication to read the information sheet, Rx Only, and details of manufacturing company.

For a more detailed description of the labelling and the package please see attachment n° 28 (label symbols), 27 (packaging), 29 (a sample of the external label we paste on the package), and 33 (a sample of the internal label we paste on the package). I attached the English version (attachment n°

15) and the Italian-English version of the information sheet we put in the packages (attachment n° 14).

Mini Implant

| BTLock device | Reference | Device name | Manufacturer |
|---------------|-----------|-------------|--------------|
| Mini Implant | K031106 | MDI | Imtec Sendac |

Description of the device

The fixture of the mini implant line is machined from titanium and self-threading. They are available in 3 diameters (2 – 2,5 – 3 mm) and 3 lengths (11,5 – 13 – 16 mm). The implant length includes the machine-cut collar (1,5 mm) and the threaded part which features a surface treatment called BT-Tite, which is obtained by the combination of sand-blasting and acid-etching.

It is available in 3 diameters (2 – 2,5 – 3 mm) and 3 lengths (11,5 – 13 – 16 mm).

The technical details of the product are included in its own drawing (see attachment n° 19).

See attachment n° 08 for the brochure of BTLock Mini Implants.

Intended use

BTLock mini implant is intended for use in the upper and/or lower jaw for immediate and long-term stabilization of removable prosthesis in order to restore chewing function to fully edentulous patients. It is intended for single use only. According to the manufacturer's surgical protocol, 4 mini implants should be inserted in order to assure the stabilization of the prosthesis.

Once the implant has been inserted, the surgeon can choose among different prosthetic components: metal ring (in case of low chewing dimension), teflon cap with plastic o-ring, metal cap with o-ring, and retaining cap.

When selecting a candidate to implant treatment, some aspects should be carefully considered: patient's expectations and motivations, his/her general health conditions, and the oral hygiene.

Labeling

The labelling for the Mini Implants is exactly the same as for the BT-Tite CV3.

For a more detailed description of the labelling and the package please see attachment n° 28 (label symbols), 27 (packaging), 30 (a sample of the external label we paste on the package), and 34 (a sample of the internal label we paste on the package). I attached the English version (attachment n° 17) and the Italian-English version of the information sheet we put in the packages (attachment n° 16).

Mini Single

| BTLock device | Reference | Device name | Manufacturer |
|---------------|-----------|------------------|---------------|
| Mini Single | K031345 | Nobel Direct 3.0 | Nobel Biocare |

Description of the device

It is a self-threaded and tapered implant made of titanium alloy. The fixture's body features BT-Tite as surface treatment (already approved by FDA, see K073458). This implant has a one-piece design, that is the abutment is integrated to the implant, and an anatomic design. The implant and the abutment are made of the same material.

It is available in 2 diameters (2,5 – 3 mm) and 4 lengths (10 – 11,5 – 13 – 16 mm). The technical details of the product are included in its own drawing (see attachment n° 20). See attachment n° 08 for the brochure of BTLock Mini Implants.

Intended use

This device it is intended to be used in maxilla or mandible in anterior narrow sites of dental arch to replace lateral teeth, dental agenesis and inferior incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. It is intended for single use only.

It requires a minimally invasive surgery and are designed for one-stage surgical procedure.

When adequate bone and attached gingival are present they can be placed by a flapless surgery.

When selecting a candidate to implant treatment, some aspects should be carefully considered: patient's expectations and motivations, his/her general health conditions, and the oral hygiene.

Labeling

The labelling for the Mini Single implants is exactly the same as for the Mini Implants.

For a more detailed description of the labelling and the package please see attachment n° 28 (label symbols), 27 (packaging), 31 (a sample of the external label we paste on the package), and 35 (a sample of the internal label we paste on the package). I attached the English version (attachment n° 17) and the Italian-English version of the information sheet we put in the packages (attachment n° 16).

Slot Implant

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| BTLock device | Reference | Device name | Manufacturer |
|---------------|-----------|--------------|--------------|
| Slot Implant | K052471 | Spider Screw | HDC S.r.l. |

Description of the device

This device is made of titanium alloy, has a tapered and self-tapping shape. The head has 2 slots, one hole and one neck. The neck is polished (in order not to interfere with soft tissue). It can be loaded immediately. Its smooth threaded surface allows easy removal at the end of treatment: as a matter of fact because complete osteointegration is neither expected nor desired with this anchorage system because its utilization is temporary.

It is available in 2 diameters (1,6 – 2 mm) and 3 lengths (6 – 7,5 – 9 mm).

See attachment n° 09 (page 58) for the description we provide of BTLock Slot Implants to our customers. The technical details of the product are included in its own drawing (see attachment n° 21).

Intended use

It is intended to be used as temporary intra-oral anchorage unit in the orthodontic treatment in the superior or inferior arch or extra arch in case of edentulous patients, when necessary teeth for the anchorage are absent or the next teeth are compromised from a parodontal point of view. It facilitates the orthodontic movement of teeth. It is removed after orthodontic treatment has been completed. It is intended for single use only. When selecting a candidate to implant treatment, some aspects should be carefully considered: patient's expectations and motivations, his/her general health conditions, and the oral hygiene.

Labeling

The labelling for the Slot implants is exactly the same as for the Mini Implants.

For a more detailed description of the labelling and the package please see attachment n° 28 (label symbols), 27 (packaging), 32 (a sample of the external label we paste on the package), and 36 (a sample of the internal label we paste on the package). I attached the English version (attachment n° 17) and the Italian-English version of the information sheet we put in the packages (attachment n° 16).

Identification of the risk analysis method

BTLock risk management is carried on according to standard 14971 UNI CEI EN ISO.

BTLock products' risks are exactly the same of predicate devices, because materials used, treatments and general mechanical properties are substantially equivalent.

Anyway, BTLock has carried on biocompatibility, mechanical tests by the Milan University (see attachment n° 38 (justification of our worst case scenario) and 39) and a multi-centred clinical study (see attachment n° 40) to prove the effectiveness of the devices before commercialization.

Biocompatibility tests include:

- Citotoxicity – Evaluation test (see attachment n° 49)
- Skin sensitization test (see attachment n° 49)
- Salmonella typhirium reverse mutation assay (see attachment n° 49)
- Intramuscular implantation test (see attachment n° 49)
- Intracutaneous reactivity test (see attachment n° 50)
- Pyrogenicity test (USP 151) (see attachment n° 51)
- Sterility (ISO 11737-2) (see attachment n° 52)
- Systemic toxicity test (see attachment n° 53)
- Evaluation of sterilization efficacy - fixture (see attachment n° 54)
- Evaluation of sterilization efficacy - abutment (see attachment n° 55)

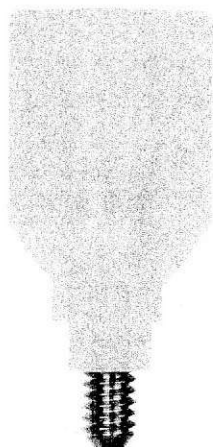
Our quality system implies a series of internal and external checks over our products.

Internal checks are described in our quality system handbook and especially in our POS (standard operational procedures) documents. External checks are the followings:

- SEM analysis (see attachment n° 57 - 58 - 59)
- Bioburden (see attachment n° 54), equivalent to Evaluation of sterilization efficacy for fixture.

We attach also the sterilization contract specifications referred to all fixtures and healing-screws (see attachment n° 56).

TEMPORARY MILLABLE ABUTMENT (BTIMCL1)

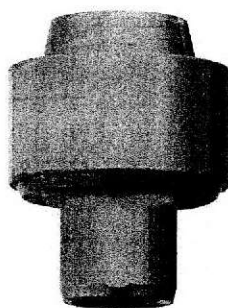


Description: abutment for the exclusive BTLock system made of plexyglass, available in 5 diameters (3,3 – 3,75 – 4,5 – 5,5 – 6,5 mm). See attachment n° 22 for technical details.

Use: it has to be used as temporary millable abutment in single or multiple restorations.

Differences from other abutments: among the BTLock abutments made of plexiglass, it is the only one that can be used as temporary.

SCREWABLE LOCK ABUTMENT (BTIMP2)



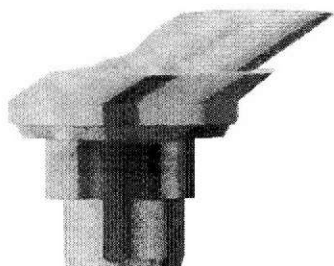
Description: lock straight neck made of titanium alloy, available in 5 diameters.

Use: indicated for disparallelism, in case of high occlusal stress and in single restorations, for bar-retained restorations and screwable technique.

Differences from other abutments: it is the straight version of BTLock abutments for screwable technique.

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SCREWABLE ANGLED ABUTMENT (A/B BTIMPI15/25)

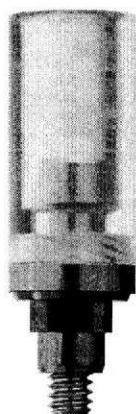


Description: lock neck made of titanium alloy. It is available in 2 inclinations (15° - 25°) and 2 heights (1 - 2,5 mm) according to the gingival thickness. See attachment n° 23 for technical details.

Use: it has to be used for disparallelism, in case of high occlusal stress and in single or multiple restorations.

Differences from other abutments: as the lock screwable abutment, it has to be used for the screwable technique.

LOCK PASSIVE ABUTMENT (BTIMP1)



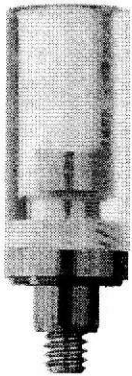
Description: passive abutment in titanium alloy, antirotational, available in 5 diameters and 3 heights (0 - 1 - 2 mm) according to the gingival thickness.

Use: suitable for single, multiple restorations and bar-retained solutions in the anterior and posterior areas.

Differences from other abutments: among the passive abutments this is the lock version.

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ROTATIONAL PASSIVE ABUTMENT (BTIMPR1)

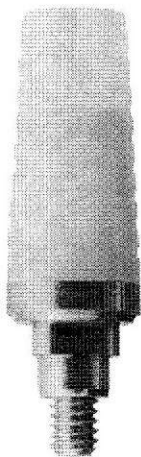


Description: passive abutment in titanium alloy, rotational, available in 5 diameters and 3 heights (0 - 1 - 2 mm) according to the gingival thickness.

Use: suitable for multiple restorations and bar-retained solutions in the anterior and posterior areas.

Differences from other abutments: among the passive abutments this is the rotational version.

IMMEDIATE-LOADING ABUTMENT WITH ROTATIONAL CAP (BTIMP3)



Description: lock abutment in titanium alloy. Cementable cap included in the package. Available in five diameters.

Use: suitable for provisional prosthetic solutions for single and multiple restorations and immediate-loading.

Differences from other abutments: in this version the

IMMEDIATE-LOADING ABUTMENT WITH FIXED CAP (BTIMP4)

Description: lock abutment in titanium alloy.
Cementable cap included in the package. Available
in five diameters.

Use: suitable for provisional prosthetic solutions for
single and multiple restorations and immediate-
loading.

Differences from other abutments: in this version the
cap is fixed.

PROVISIONAL LOCK ABUTMENT FOR IMMEDIATE LOAD (BTIPML1)

Description: lock abutment in titanium alloy. The
retention grooves help to fix the acrylic material of
the provisional prosthesis. Available in five
diameters. See attachment n° 24 for technical
details.

Use: to be used for provisional prosthesis in single
restorations and for immediate-loading.

Differences from other abutments: this lock version
is for single restorations.

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PROVISIONAL ROTATIONAL ABUTMENT FOR IMMEDIATE LOAD (BTIPMR1)



Description: rotational abutment in titanium alloy. The retention grooves help to fix the acrylic material of the provisional prosthesis. Available in five diameters. See attachment n° 25 for technical details.

Use: to be used for provisional prosthesis in multiple restorations and for immediate-loading.

Differences from other abutments: the rotational version is for multiple restorations.

Please, see attachment n° 37 for a sample of the labelling for prosthetic components (which reports information about: the product description, product code, size (diameter and length), manufacturing date, batch number, CE mark, one time use mark, details of manufacturing company) and the information sheet. For these devices gamma-ray sterilization is not necessary, this is the reason why labelling is much more simpler.

Instrumentation is exempt from 510K. Anyway, in case you need the technical drawings or some information about the accessories necessary to insert these implants, do not hesitate to contact me.

Ester Battilana

BTLock S.r.l.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 27 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ester Battilana
BTLock s.r.l.
Via Madonnetta, 97/C
36041 ALTE di MONTECCHIO MAGGIORE
VICENZA, ITALY

Re: K083869
Trade/Device Name: BT-Tite CV3, Mini Implant, Mini Single, Slot Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE & NHA
Dated: March 18, 2009
Received: March 18, 2009

Dear Ms. Battilana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

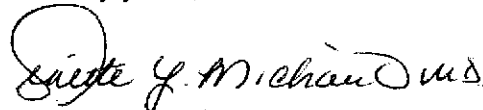
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K083869

Indications for Use

Device Name: **BT-Tite CV3, Mini Implant, Mini Single, Slot Implant**

Indications for Use:

BT-Tite CV3: It is intended to be used in maxilla or mandible, for post-extraction sites and where the implant would be immediately loaded. It is intended to be used in a single stage or two stage surgical procedure.

Mini Implant: It is intended to be used in maxilla or mandible for immediate and long-term stabilization of removable prosthesis.

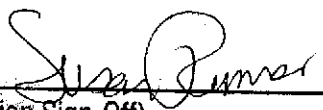
Mini Single: It is intended to be used in maxilla or mandible in anterior narrow sites of dental arch, to replace lateral teeth, dental agenesis and inferior incisors.

Slot implant: It is intended to be used as temporary intra-oral anchorage unit in the orthodontic treatment in the superior or inferior arch or extra arch in case of edentulous patients, when necessary teeth for the anchorage are absent or the next teeth are compromised from a parodontal point of view. It facilitates the orthodontic movement of teeth. It is removed after orthodontic treatment has been completed. Slot implants are intended for single use only.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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